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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|-----------------------|-------------------------|------------------|
| 09/973,562 | 10/09/2001 | Joseph P. Desmond III | BSC-186 | 6009 |
| 21323 7 | 590 04/02/2003 | | | |
| • | WITZ & THIBEAU | , EXAMINER | | |
| HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110 | | | MATTHEWS, WILLIAM H | |
| BOSTON, MA | 02110 | • | ART UNIT | PAPER NUMBER |
| | | | 3738 、 | 6 |
| | | | DATE MAILED: 04/02/2003 | , |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Λ, | | | |
|---|---|---|--|--|--|
| | Application No. | Applicant(s) | | | |
| | 09/973,562 | DESMOND ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | William H. Matthews (Howie) | 3738 | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the | correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 36(a). In no event, however, may a reply be to y within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from to, cause the application to become ABANDON | imely filed ys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133). | | | |
| 1) Responsive to communication(s) filed on 21. | January 2003 . | | | | |
| 2a)☐ This action is FINAL . 2b)⊠ Th | is action is non-final. | | | | |
| 3) Since this application is in condition for allowed closed in accordance with the practice under | | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 1-37 is/are pending in the application4a) Of the above claim(s) 13-16 and 19-37 is/a | | | | | |
| | ne williarawii ilom consideration | | | | |
| 5)[_] Claim(s) is/are allowed. 6)⊠ Claim(s) <u>1-12,17 and 18</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examine | F. | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ acce | pted or b) objected to by the Exa | aminer. | | | |
| Applicant may not request that any objection to th | e drawing(s) be held in abeyance. | See 37 CFR 1.85(a). | | | |
| 11) The proposed drawing correction filed on | _ is: a)□ approved b)□ disappr | roved by the Examiner. | | | |
| If approved, corrected drawings are required in re | ply to this Office action. | | | | |
| 12) ☐ The oath or declaration is objected to by the Ex | aminer. | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign | n priority under 35 U.S.C. § 119(| a)-(d) or (f). | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority document | s have been received. | | | | |
| 2. Certified copies of the priority document | s have been received in Applica | tion No | | | |
| 3. Copies of the certified copies of the prio application from the International Bu * See the attached detailed Office action for a list | reau (PCT Rule 17.2(a)). | | | | |
| 14) ☐ Acknowledgment is made of a claim for domesti | ic priority under 35 U.S.C. § 119 | (e) (to a provisional application). | | | |
| a) The translation of the foreign language pro | * = | | | | |
| Attachment(s) | - | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 | 5) 🔲 Notice of Informa | ry (PTO-413) Paper No(s) I Patent Application (PTO-152) | | | |
| | | | | | |

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DETAILED ACTION

Election/Restrictions

- 1. Applicant's election of Group I, and furthermore Figures 1-4, drawn to claims 1-12,17,18 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 13-16 and 19-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1-12 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "the first and second ends". This limitation is unclear whether reference is made to previously recited "first and second terminal ends" or new "ends". Claims 2-12 and 17-18 are rejected for depending from a rejected base claim.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-3,11-12,17,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Voss US PN 4,994,066.

Voss discloses in figures 1-2 and 6-7 a compressible stent having collapsed and expanded states for placement in the prostatic urethra having two terminal ends having larger diameters than an intermediate portion.

Regarding claims 11-12, either end of stent (10) may be considered the first end.

Regarding claims 17-18, radiopaque materials and coatings are described in lines 18-24 of col. 5 and lines 9-20 of col. 6.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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8. Claims 4-5,7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, and in further view of Zilber US PN 4,955,859.

Voss discloses a prostatic stent as described above meeting the structural limitations of claims 4-5 and 7-9, but lacks the express disclosure of retention rings having annular elastic cores and expanded and collapsed states. Zilber teaches in lines 16-42 of col. 6, lines 47-66 of col. 7, and lines 5-35 of col. 9 a prostatic stent having sidewalls of rubber elastomers, as does Voss, and adds retention rings with annular elastic cores along the length of the stent to provide reinforcement of the stent once implanted.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elastomer stent disclosed by Voss to include the retention rings taught by Zilber in order to provide sufficient reinforcement once the stent is implanted.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, in view of Zilber US PN 4,955,859 as applied to claims 4-5, and in further view of Yachia et al. US PN 5,246,445.

Voss as modified by Zilber teaches a prostatic stent as described above meeting the structural limitations of claim 6, but lacks the express disclosure of the retention rings having annular elastic cores made of a nickel titanium alloy. Yachia teaches in lines 29-52 of col. 4 that prostatic stents are well known to use construction materials such as nickel titanium because of its biocompatibility.

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Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Voss, as modified by Zilber, to select nickel titanium as the spring material, as taught by Yachia et al. to provide good biocompatibility once the stent is implanted.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, and in further view of Garber US PN 5,269,802.

Voss discloses a prostatic stent, as described above, meeting the structural limitations of claim 10, but lacks the express disclosure of apertures located in the sidewalls. Garber teaches in figure 2 and lines 67 of col. 4 through line 8 of col. 5 a prostatic stent having sidewalls with apertures to provide fluid communication and facilitate urinary incontinence.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Voss by incorporating apertures in the sidewalls as taught by Garber to provide fluid communication and facilitate urinary incontinence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM March 31, 2003

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700